MAY - 1 2001

510(k) Summary K010439

Submitter Name	Terang Nusa Sdn Bhd
Submitter Address	1 , Jalan 8 Pengkalan Chepa 2 Industrial Zone 16100 Kota Bharu, Kelantan , Malaysia.
Submitter Telephone	+60 9 7735133
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Contact Person	LOW , Chin Guan
Date of preparation	28 Dec 2000
Trade Name	MAXITEX Duplex
Common Name	Sterile Surgical gloves prepowdered. Contain less than 100 microgram/gram of water extractable protein.
Classification	Surgeon's Glove
Legally marketed device to which substantial equivalence is being claimed.	The MAXITEX Duplex surgical glove described in this 510(k) is substantially equivalent to the SUR-G GLOV Surgical Gloves that is currently marketed.
Description of device	MAXITEX Duplex meets the requirements for surgical gloves described by the American Standard for Testing and Material ASTM D3577-00.
Intended Use of the device	MAXITEX Duplex surgical gloves are disposable and sterile devices intended to be worn by healthcare personnel to prevent cross contamination between the user and the patient during procedures.

510 K Summary (continued)

Brief description of non-clinical tests	Test conducted per ASTM D3577-00, ASTM D512 indicates that the product meet the requirements. Primary Skin Irritation test ASTM F 719-81 and Dermal Sensitization Test ASTM F 720-81 (86) indicates no sensitization or irritation.
Brief description of clinical tests	Not required
Conclusion drawn from clinical and non clinical tests	It can be concluded that MAXITEX Duplex surgical glove, prepowdered, will perform according to the performance standards referenced and therefore meets ASTM standards., FDA requirements and labeling claims. This device is substantially equivalent to the currently marketed devices.
Additional information deemed necessary by the FDA	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chin-Guan Low
Managing Director
Terang Nusa SDN BHD
1, Jalan 8, Pengkalan Chepa
2 Industrial Zone
16100 Kota Bharu, Kelantan
MALAYSIA

Re: K010439
Trade/Device Name: Maxitex Duplex Sterile Latex Powdered Surgeon Gloves with Protein Labeling Claim (100 Micrograms or Less)
Regulation Number: 878.4460
Regulatory Class: I
Product Code: KGO
Dated: February 4, 2001
Received: February 12, 2001

Dear Mr. Low:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug

Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devcies
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indication for use Statement

Submitter	:	Terang Nusa Sdn Bhd
510(k) Number	:	
Device Name	:	Latex Surgical Glove prepowdered. Contain less than 100 microgram / gram of water extractable protein
Trade Name	:	MAXITEX Duplex
Indication for use	:	

These surgeon's gloves are worn by operating room personnel to protect a surgical wound from contamination .

Concurrence of CDHR Office of Device Evaluation (ODE)

Lisa S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010439

Prescription Use _____ *OR* Over the counter_____
Per 21 CFR 801.10